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FILING DATE.

APPLICATION NUMBER: 60/424,709

FILING DATE: November 08, 2002

RELATED PCT APPLICATION NUMBER: PCT/US03/18053



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**PROVISIONAL APPLICATION FOR PATENT COVER SHEET**

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

Express Mail Label No.

**INVENTOR(S)**

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Orhun K. William H.	Muratoglu Harris	Cambridge, MA Belmont, MA

☐ Additional inventors are being named on the \_\_\_\_\_ separately numbered sheets attached hereto**TITLE OF THE INVENTION (500 characters max)**

METAL BACK OR MESH CROSSLINKING

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**ENCLOSED APPLICATION PARTS (check all that apply)**☒ Specification Number of Pages

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☐ Other (specify)☐ Application Data Sheet. See 37 CFR 1.76**METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT**☐ Applicant claims small entity status. See 37 CFR 1.27.☒ A check or money order is enclosed to cover the filing feesFILING FEE  
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160

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

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Date

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REGISTRATION NO.  
(if appropriate)

33,715

Docket Number:

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# FEE TRANSMITTAL for FY 2002

Patent fees are subject to annual revision

Complete if Known

Application Number Unassigned  
Filing Date November 8, 2002  
First Named Inventor Orhun K. Muratoglu  
Examiner Name Unassigned  
Group / Art Unit Unassigned  
Attorney Docket No 37697-0068

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TOTAL AMOUNT OF PAYMENT (\$) 160

## METHOD OF PAYMENT (check all that apply)

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## FEE CALCULATION

### 1. BASIC FILING FEE

Large Fee Code	Entity Fee (\$)	Small Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
101	740	201	370	Utility filing fee	
106	330	206	165	Design filing fee	
107	510	207	255	Plant filing fee	
108	740	208	370	Reissue filing fee	
114	160	214	80	Provisional filing fee	160

SUBTOTAL (1)

(\$ 160)

### 2. EXTRA CLAIM FEES

Total Claims  - \*\* =  X  =   
Independent Claims  - \*\* =  X  =   
Multiple Dependent  X  =

Large Fee Code	Entity Fee (\$)	Small Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
103	18	203	9	Claims in excess of 20	
102	84	202	42	Independent claims in excess of 3	
104	280	204	140	Multiple dependent claim, if not paid	
109	84	209	42	** Reissue independent claims over original patent	
110	18	210	9	** Reissue claims in excess of 20 and over original patent	

SUBTOTAL (2)

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\*\*or number previously paid, if greater, For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Fee Code	Entity Fee (\$)	Small Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	400	216	200	Extension for reply within second month	
117	920	217	460	Extension for reply within third month	
118	1,440	218	720	Extension for reply within fourth month	
128	1,960	228	980	Extension for reply within fifth month	
119	320	219	160	Notice of Appeal	
120	320	220	160	Filing a brief in support of an appeal	
121	280	221	140	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,280	241	640	Petition to revive - unintentional	
142	1,280	242	640	Utility issue fee (or reissue)	
143	460	243	230	Design issue fee	
144	620	244	310	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Processing fee under 37 CFR 1 17 (q)	
126	180	126	180	Submission of Information Disclosure Sheet	
581	40	581	40	Recording each patent assignment per property (timea number of properties)	
146	740	246	370	Filing a submission after final rejection (37 CFR § 1 129(a))	
149	740	249	370	For each additional invention to be examined (37 CFR § 1 129(b))	
178	740	278	370	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	

Other fee (specify) \_\_\_\_\_

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3)

(\$ 0)

## SUBMITTED BY

Name (Print/Type)	Registration No. Attorney/Agent)	Telephone
John P. Pearson	33,715	202 912 2000
Signature		Date November 8, 2002

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Attorney Docket No.: 37697-0068

Inventors: Orhun K. Muratoglu  
William H. Harris

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## METAL BACK OR MESH CROSSLINKING

This application relates to U. S. Serial No. 60/390,120, filed June 21, 2002, the entirety of which is hereby incorporated by reference.

10

### Field of the Invention

The present invention relates to a medical implant that comprises polymeric material that is in contact (which includes close proximity and touching) with another piece (such as a metallic mesh or back, a non-metallic mesh or back, a tibial tray, a patella tray, or an acetabular shell), thereby forming an interface. Methods of manufacturing and sterilizing such devices and materials used therein also are provided.

### Background of the Invention

Increased crosslink density in polyethylene is desired in bearing surface applications for joint arthroplasty because it significantly increases the wear resistance of this material. The preferred method of crosslinking is by exposing the polyethylene to ionizing radiation. However, ionizing radiation, in addition to crosslinking, also will generate residual free radicals, which are the precursors of oxidation-induced embrittlement. This is known to adversely affect *in vivo* device performance. Therefore, it is desirable to reduce the concentration of residual free radicals, preferably to undetectable levels, following irradiation so as to avoid long-term oxidation.

Methods of irradiating polymers are described in U.S. Patent No. 5,897,400. In general, this patent describes medical prosthesis formed, at least in part, of a melt-irradiated crosslinked high molecular weight polyethylene. The disclosed melt-

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irradiation process improves the wear resistance of the polymer, thus addressing the problem of severe adverse effects associated with the use of less wear resistant polymers. U.S. Patent No. 5,897,400 describes, among other things, heating the polymers to or above the melting point, irradiating the polymer, and cooling the polymer.

5 International Application No. PCT/US97/02220 (WO 97/29793) also describes the irradiation of polymers that are useful in the orthopedic field. In this application, several methods of increasing the wear characteristics of polymers are described. The application describes, among other things, an irradiation procedure  
10 wherein the polymer is irradiated at room temperature or below. Following irradiation, the polymer can be heated to or above the melting temperature to remove any residual free radicals through the process of recombination. The application also describes another irradiation method in which the polymer is pre-heated to a temperature above room temperature, but below the melting temperature, and  
15 irradiated. Following irradiation, the polymer may be subsequently melted by heating it to the melting temperature or above to substantially eliminate any detectable free radicals via the process of recombination.

WO 97/29793 also describes methods of irradiating polymers in which the heat generated by the irradiation is sufficient to at least partially melt the polymer, and  
20 is described as "adiabatic" melting or heating. Adiabatic melting or heating refers to heating induced by radiation, which leads to an increase of the temperature of the polymer with substantially little loss of heat to the surroundings. The application describes an adiabatic melting method, among other things, in which the polymer is preheated to a temperature below the melting point, then irradiated with enough total  
25 dose and at a high enough dose rate to at least partially melt the polymer crystals. Subsequent to this warm-irradiation, the polymer also can be heated to or above the melting temperature such that any residual free radicals are eliminated. The application also describes another irradiation, adiabatic melting method that is similar to the method described above, except that the polymer is provided at room  
30 temperature or below.

It is important that crosslinked ultra-high molecular weight polyethylene (UHMWPE) based medical devices are sterilized after they are packaged for *in vivo* use. There are several methods of sterilization that can be utilized for medical implants, such as the use of ethylene oxide, gas plasma, heat (autoclave), or radiation.

5 However, applying heat to a packaged polymeric medical product can destroy either the integrity of the packaging material (particularly the seal, which is provided to prevent bacteria and other contaminants from entering the package after the sterilization step) or the product itself. Because ethylene oxide may adversely impact environmental and employee safety, gamma ray, x-ray or electron beam radiation has

10 been utilized as a preferred means of sterilization. These types of radiation use a high-energy beam to destroy or inactivate bacteria, viruses, and other microbial species that contaminate the packaged medical products.

However, it has been recognized that regardless of the radiation type, the high-energy beam causes generation of free radicals in polymers during irradiation. It also

15 has been recognized that the amount of free radicals generated is dependent upon the radiation dose received by the polymers and that the distribution of free radicals in the polymeric implant depends upon the geometry of the component, the type of polymer, the dose rate, and the type of radiation.

Currently available methods of sterilization of medical devices containing

20 polymeric materials include use of ethylene oxide (EtO) or gas plasma (GP). Although EtO and GP are successfully used in sterilizing certain polymeric implants, despite environmental and safety concerns, there are some implant designs where these gas sterilization methods will not work. These medical implants often contain factory-assembled pieces (usually a metallic or ceramic component) that are in close

25 contact with the UHMWPE. In most cases, the interface is not accessible to the EtO gas or the GP. Therefore, these implants must be sterilized by gamma radiation, in air or in inert atmospheres. Yet these methods generate enough residual free radicals to adversely affect device performance in the long-term. With the recent introduction of radiation and thermal treatment of UHMWPE to improve its wear behavior and its

30 long-term stability, gamma sterilization is no longer favored. In view of the

limitations of the commercialized processes, new approaches are needed that will provide an alternative method of manufacturing crosslinked polymeric material (for example, UHMWPE)-based medical implants in configurations wherein the polymeric component is in close contact with another piece (such as another component, for example, a metallic or a non-metallic component).

The current invention, therefore, provides improved methods of making and sterilizing medical implants that contains highly cross-linked polymeric material, wherein the polymeric component (for example, UHMWPE) is in close contact with another piece (such as another component, for example, a metallic or a non-metallic component).

#### Summary of the Invention

The present invention relates generally to methods of manufacturing and sterilizing medical implants comprising a polymeric material, such as cross-linked ultra-high molecular weight polyethylene (UHMWPE), that is in contact with another piece (generally a metallic piece), thereby forming an interface, for example, an interlocking interface.

In one aspect, the invention provides methods of making a medical implant containing crosslinked polyethylene, for example, ultra-high molecular weight polyethylene (UHMWPE) that is in contact with another piece, thereby forming an interface, comprising the steps of: a) compression molding of polyethylene, including powder, flakes and particles to another piece, thereby forming an interlocked hybrid material; b) irradiating the hybrid material by ionizing radiation; and c) reducing free radicals in the crosslinked polyethylene by heating the hybrid material above the melting point of the crosslinked polyethylene. Polyethylene sheets also can be employed, but they may not result in the attainment of interlocking interfaces.

The metallic or non-metallic back or mesh as described, in one aspect of the invention, is shaped to serve as a fixation interface with the bone, through either bony growth or by bone cement, wherein the shapes are in the form of acetabular liner,

In another aspect, the invention includes methods of making a medical implant containing crosslinked polyethylene, for example, UHMWPE, that is in contact with another piece, thereby forming an interface, wherein the polyethylene, including powder, flakes and particles are compression molded to a metallic mesh, wherein the metallic mesh is shaped to serve as a fixation interface with the bone, through either bony growth or by bone cement, wherein the shapes are, for example, in the form of acetabular liner, tibial tray for total or unicompartamental knee implants, patella tray, glenoid component, ankle, elbow or finger component.

In another aspect, the invention provides methods of making medical devices including bipolar hip replacements, tibial knee inserts with reinforcing metallic and polyethylene posts, and an implant that contains an interface that cannot be sterilized by a gas sterilization method.

20 In another aspect, the invention provides methods of: sterilizing a medical implant containing crosslinked polyethylene that is in contact with another piece, thereby forming an interface, wherein the methods comprise the steps of a) compression molding of polyethylene, such as resin powder, flakes and particles to another piece, thereby forming an interlocked hybrid material; b) irradiating the  
25 hybrid material by ionizing radiation; c) reducing free radicals in the crosslinked polyethylene by heating the hybrid material above the melting point of the crosslinked polyethylene; and d) sterilizing the medical implant with a gas.

5



gas plasma, or the other gas, wherein ethylene oxide, gas plasma, or the other gas, is used for gas sterilization.

In another aspect, the invention provides medical implants, comprising crosslinked polyethylene that is in contact with another piece, thereby forming an interface, made by processes comprising the steps of: a) compression molding of polyethylene, such as resin powder, flakes and particles to another piece, thereby forming an interlocked hybrid material; b) irradiating the hybrid material by ionizing radiation; and c) reducing free radicals in the crosslinked polyethylene by heating the hybrid material above the melting point of the crosslinked polyethylene.

In another aspect, the invention provides medical implants, comprising crosslinked polyethylene that is in contact with another piece, thereby forming an interface, made by processes comprising the steps of: a) compression molding of polyethylene, such as resin powder, flakes and particles to another piece, thereby forming an interlocked hybrid material; b) irradiating the hybrid material by ionizing radiation; and c) reducing free radicals in the crosslinked polyethylene by heating the hybrid material above the melting point of the crosslinked polyethylene.

In another aspect, the invention provides interfaces made by processes comprising the steps of: a) compression molding of polyethylene, such as resin powder, flakes and particles to another piece, thereby forming an interlocked hybrid material; b) irradiating the hybrid material by ionizing radiation; and c) reducing free radicals in the polyethylene by heating the hybrid material above the melting point of the polyethylene.

In another aspect, the invention provides interfaces made by processes comprising the steps of: a) compression molding of polyethylene to another piece, thereby forming an interlocked hybrid material; b) irradiating the hybrid material by ionizing radiation; and c) reducing free radicals in the polyethylene by heating the hybrid material above the melting point of the polyethylene.

In another aspect, the invention provides interfaces made by processes comprising the steps of: a) compression molding of polyethylene, such as resin powder, flakes and particles to another piece, thereby forming an interlocked hybrid

material; and b) irradiating the hybrid material by ionizing radiation, wherein the interface is rendered substantially sterile.

In another aspect, the invention provides interfaces made by processes comprising the steps of: a) compression molding of polyethylene, such as resin  
5 powder, flakes and particles to another piece, thereby forming a mechanically interlocked hybrid material; and b) irradiating the hybrid material by ionizing radiation, wherein the interface is rendered substantially sterile.

In another aspect, the invention provides interfaces made by processes comprising the steps of: a) compression molding of polyethylene, such as resin  
10 powder, flakes and particles to another piece, thereby forming an interlocked hybrid material; b) irradiating the hybrid material by ionizing radiation; and c) reducing free radicals in the polyethylene by heating the hybrid material above the melting point of the polyethylene, wherein the interface is rendered substantially sterile.

In another aspect, the invention provides interfaces made by processes  
15 comprising the steps of: a) compression molding of polyethylene, such as resin powder, flakes and particles to another piece, thereby forming an interlocked hybrid material; b) irradiating the hybrid material by ionizing radiation; and c) reducing free radicals in the polyethylene by heating the hybrid material above the melting point of the polyethylene, wherein the interface is rendered substantially sterile.

20 In another aspect, the invention provides acetabular assemblies comprising: a) polyethylene powder compression molded to another piece, thereby forming an interlocked hybrid material; b) a substantially sterile interface; and c) a metallic back.

In another aspect, the invention provides acetabular assemblies comprising: a)  
a polyethylene acetabular liner compression molded to another piece, thereby forming  
25 a mechanically interlocked hybrid material; b) a substantially sterile interface; and c) a metallic back.

Another aspect of the invention provides medical implants comprising  
crosslinked polyethylene having substantially no detectable free radicals; and at least  
one substantially sterile interface, for example, a substantially sterile mechanically  
30 interlocking interface.

Another aspect of the invention provides medical implants comprising crosslinked polyethylene having substantially no detectable free radicals; and a sterile mechanically interlocking interface, wherein polyethylene, such as resin powder, flakes and particles are compression molded to another piece, for example, a metallic mesh or back, a non-metallic mesh or back such as ceramic mesh or back, a tibial tray, a patella tray, or an acetabular shell.

The heating temperature of the compressed polyethylene or the hybrid components are above the melting point of the polyethylene, preferably above about 137°C and the radiation dose at the melt is between about 25 kGy and about 1000 kGy. The radiation dose can be about 50 kGy, about 100 kGy, about 200 kGy, about 300 kGy, about 400 kGy, about 500 kGy, about 600 kGy, about 700 kGy, about 800 kGy, about 900 kGy, or about 1000 kGy.

In one aspect of the invention, the heating of the hybrid material above the melting point of the polyethylene is carried out in air, wherein the air contains between about 1% and about 22% oxygen. In a preferred aspect of the invention, the heating is carried out in air containing between about 2% and about 21% oxygen.

In another aspect, the heating of the hybrid material above the melting point of the polyethylene is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

In another aspect, the heating of the hybrid material above the melting point of the polyethylene is carried out in a vacuum.

The counterface piece as described, in one aspect of the invention, comprises a metal or a non-metal, wherein the piece is a metallic mesh or back, a ceramic mesh or back, a tibial tray, a patella tray, or an acetabular shell, wherein the piece comprises a metallic mesh or back, a non-metallic mesh or back, an undercut, a recess or a combination thereof.

The interfaces as described in one aspect of the invention, comprise a metal-polymer, wherein the polymer is a polyolefin, wherein the polyolefin is selected from a group consisting of a low-density polyethylene, high-density polyethylene, linear

low-density polyethylene, ultra-high molecular weight polyethylene (UHMWPE), or mixtures thereof.

In another aspect, the invention provides methods of sterilization, wherein the implant comprises medical devices selected from the group consisting of bipolar hip  
5 replacements, tibial knee inserts with reinforcing metallic and polyethylene posts, and an implant that contains an interface that cannot be readily sterilized by a gas sterilization method.

In one aspect of the invention, the ionizing radiation includes gamma or ionizing irradiation in air, wherein the air contains between about 1% and about 22%  
10 oxygen. In a preferred aspect of the invention, the radiation is carried out in air containing between about 2% and about 21% oxygen.

In another aspect, the ionizing radiation includes gamma or ionizing irradiation in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination  
15 thereof.

In another aspect, the ionizing radiation includes gamma or ionizing irradiation in a vacuum.

Following irradiation, the reduction of free radicals in the crosslinked polyethylene is achieved by heating the implants to above the melting temperature of  
20 the polyethylene, wherein the polyethylene can be in contact with a non-oxidizing medium, wherein the non-oxidizing medium is an inert gas or an inert fluid, wherein the medium is a polyunsaturated hydrocarbon selected from the group consisting of: acetylenic hydrocarbons such as acetylene; conjugated or unconjugated olefinic hydrocarbons such as butadiene and (meth)acrylate monomers; and sulphur  
25 monochloride with chloro-tri-fluoroethylene (CTFE) or acetylene.

In one aspect of the invention, the reduction of free radicals in crosslinked polyethylene is achieved in air, wherein the air contains between about 1% and about 22% oxygen. In a preferred aspect of the invention, the radiation is carried out in air containing between about 2% and about 21% oxygen.

In another aspect, the reduction of free radicals in crosslinked polyethylene is achieved in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

5 In another aspect, the reduction of free radicals in crosslinked polyethylene is achieved in a vacuum.

In one aspect, the invention provides medical implants comprising crosslinked polyethylene having substantially no detectable free radicals; and a sterile interface such as a mechanically interlocking interface. The polyethylene of the implant as  
10 described herein is in contact with another piece, thereby forming an interface, wherein the polyethylene, such as resin powder, flakes and particles are compression molded to another piece, for example, a metal or a non-metal, thereby forming a mechanically interlocked hybrid material.

The implant as described herein is compression molded, wherein  
15 polyethylene, such as resin powder, flakes and particles are compression molded to another piece, for example, a metallic mesh or back, or a non-metallic mesh or back such as a ceramic mesh or back, a tibial tray, a patella tray, or an acetabular shell.

The implant as described herein comprises a metal-polymer interface, wherein the metal piece comprises a metallic mesh or back, or a non-metallic mesh or back  
20 such as a ceramic mesh or back, an undercut, a recess or a combination thereof, thereby forming a mechanically interlocked hybrid material.

#### **Brief Description of the Drawings**

Figures 1A-1C show sequential steps in compression molding of polyethylene  
25 powder (10) to a metallic mesh (20).

Figure 2A illustrates compression molded of polyethylene (60) on a metallic back (40) containing a metallic mesh (20) and a metallic backed Patella (70). Figure 2B shows compression molded of polyethylene (120) on a metal shell (100)

containing metallic mesh (20). Figure 2C and 2D show a metal tray (40) having mesh (20) or a an undercut (80), respectively.

Figure 3 shows a schematic diagram of compression apparatus set up.

Figure 4 depicts a typical mesh incorporated into UHMWPE pin by high  
5 temperature compression.

Figure 5 illustrates a mesh incorporated into polyethylene by compression molding polyethylene resin powder.

Figure 6 depicts an example of mesh retention in the polyethylene resin/mesh assembly following irradiation and subsequent melting: (Figure 6A) post-irradiation  
10 before melting and (Figure 6B) post-irradiation after melting of the same pin.

#### **Detailed Description of the Invention**

The present invention relates generally to methods of manufacturing and sterilizing medical implants comprising a polymeric material, such as cross-linked  
15 ultra-high molecular weight polyethylene (UHMWPE), that is in contact with another piece (for example, a metallic or non-metallic component), thereby forming an interlocking interface.

One aspect of the invention relates to the following processing steps to fabricate medical devices made out of highly crosslinked UHMWPE and containing  
20 metallic pieces such as bipolar hip replacements, tibial knee inserts with reinforcing metallic and polyethylene posts, and for any implant that contains a surface that cannot be readily sterilized by a gas sterilization method.

According to one aspect of the invention, the UHMWPE component of a medical implant is in close contact with another material (such as a metallic mesh or  
25 back, a non-metallic mesh or back, a tibial tray, a patella tray, or an acetabular shell), wherein polyethylene, such as resin powder, flakes and particles are directly compression molded to these counterfaces. For example, a polyethylene tibial insert is manufactured by direct compression molding of polyethylene resin powder to a tibial tray, to a metallic mesh or back or to a non-metallic mesh or back. In the latter

case, the mesh is shaped to serve as a fixation interface with the bone, through either bony in-growth or the use of an adhesive, such as PMMA bone cement. These shapes are of various forms including, acetabular liner, tibial tray for total or unicompartmental knee implants, patella tray, and glenoid component, ankle, elbow or  
5 finger component. One aspect of the invention relates to mechanical interlocking of the molded polyethylene with the other piece(s), for example, a metallic or a non-metallic piece, that makes up part of the implant.

Another aspect of the invention provides methods for achieving mechanically interlocked medical devices. For example, a mesh-like surface on the other side facing  
10 the polyethylene powder is compression molded and the consolidated polyethylene takes a shape at the interface that penetrates into the mesh. The mesh surface on the other side can be continuous through the interface or intermittent (see Figure 1A-1C).

Another aspect of the invention includes surfaces with geometries, for example, undercuts, grooves (see Figure 2D), or the like that allows the polyethylene,  
15 such as resin powder, flakes and particles to penetrate, consolidate and take the shape of the surface such that the mechanical interlocking achieved allows for a strong interface (see Figure 1C).

Another aspect of the invention provides combination of interface surfaces, for example, a mesh and macro-geometries are combined to tailor an interface of  
20 preferred strength (see Figure 2A).

The interface geometry is crucial in that polyethylene assumes the geometry as its consolidated shape. UHMWPE has a remarkable property of 'shape memory' due to its very high molecular weight that results in a high density of physical entanglements. Following consolidation, plastic deformation introduces a permanent  
25 shape change, which is almost completely reversed by melting. This recovery of the original consolidated shape is due to the 'shape memory', which is triggered by melting.

Another aspect of the invention provides that following the direct compression moldings of the polyethylene to the counterface with the mechanical interlock, the  
30 hybrid component is irradiated using ionizing radiation to a desired dose level, for

example, about 25 kGy to about 1000 kGy, preferably between about 50 kGy and about 100 kGy. In accordance with aspects of the invention, the invention discloses that while the irradiation crosslinks the polymer, it also sterilizes the interfaces, that is the close contact between the polyethylene and the counterface. Another aspect of the invention discloses that the irradiation step generates residual free radicals and therefore, a melting step is introduced thereafter to quench the residual free radicals. Since the polyethylene is consolidated into the shape of the interface, thereby setting a 'shape memory' of the polymer, the polyethylene does not separate from the counterface.

10 In another aspect of the invention, there are provided methods of crosslinking polyethylene, to create a UHMWPE-based medical device, wherein the device is immersed in a non-oxidizing medium such as inert gas or inert fluid, wherein the medium is heated to above the melting point of the irradiated polyethylene, for example, UHMWPE (above about 137°C) to eliminate the crystalline matter and to allow the recombination/elimination of the residual free radicals. Because the shape memory of the compression molded polymer is set at the mechanically interlocked interface and that memory is strengthened by the crosslinking step, there is no significant separation at the interface between the polyethylene and the counterface.

20 Another aspect of the invention provides that following the above steps of free radical elimination, the interface between the metal and the polymer become sterile due to the high irradiation dose level used during irradiation. When there is substantial oxidation on the outside surface of the polyethylene induced during the free radical elimination step or irradiation step, the device surface can be further machined to remove the oxidized surface layer. In another aspect, the invention provides that in the case of a post-melting machining of an implant, the melting step is carried out in the presence of an inert gas.

25 Another aspect of the invention includes methods of sterilization of the fabricated device, wherein the device is further sterilized with ethylene oxide, gas plasma, or the other gases, when the interface is sterile but the rest of the component is not.

30



The term "compression molding" as referred herein related generally to what is known in the art and specifically relates to molding applicable in polyethylene-based devices, for example, medical implants wherein polyethylene in any physical state, including powder form, is compressed to solid support, for example, a metallic back, 5 metallic mesh, or metal surface containing grooves, undercuts, or cutouts. The compression molding also includes high temperature compression molding of polyethylene at various states, including resin powder, flakes and particles, to make a component of a medical implant, for example, a tibial insert, an acetabular liner, a glenoid liner, a patella, or an unicompartmental insert, to the counterface.

10 The term "mechanically interlocked" refers generally to interlocking of polyethylene and the counterface, that are produced by various methods, including compression molding, heat and irradiation, thereby forming an interlocking interface, resulting into a 'shape memory' of the interlocked polyethylene. Components of a device having such an interlocking interface can be referred to as a "hybrid material". 15 Medical implants having such a hybrid material, contain a substantially sterile interface.

The term "substantially sterile" refers to a condition of an object, for example, an interface or a hybrid material or a medical implant containing interface(s), wherein the interface is sufficiently sterile to not result in infection or require revision surgery.

20 "Metallic mesh" refers to a porous metallic surface of various pore sizes, for example, 0.1-3 mm. The porous surface can be obtained through several different methods, for example, sintering of metallic powder with a binder that is subsequently removed to leave behind a porous surface; sintering of short metallic fibers of diameter 0.1-3 mm; or sintering of different size metallic meshes on top of each other 25 to provide an open continuous pore structure.

"Bone cement" refers to what is known in the art as an adhesive used in bonding medical devices to bone. Typically, bone cement is made out of polymethylmetacrylate (PMMA).

30 "High temperature compression molding" refers to the compression molding of polyethylene in any form, for example, resin powder, flakes or particles, to impart

new geometry under pressure and temperature. During the high temperature (above the melting point of polyethylene) compression molding, polyethylene is heated to above its melting point, pressurized into a mold of desired shape and allowed to cool down under pressure to maintain a desired shape.

5 "Shape memory" refers to what is known in the art as the property of polyethylene, for example, an UHMWPE, that attains a preferred low energy shape when melted. The preferred low energy shape is achieved when the resin powder is consolidated through compression molding.

10 The phrase "substantially no detectable residual free radicals" refers to a state of a polyethylene component, wherein enough free radicals are eliminated to avoid oxidative degradation, which can be evaluated by electron spin resonance (ESR). The lowest level of free radicals detectable with state-of-the-art instruments is about  $10^{14}$  spins/gram and thus the term "detectable" refers to a detection limit of  $10^{14}$  spins/gram by ESR.

15 The terms "about" or "approximately" in the context of numerical values and ranges refers to values or ranges that approximate or are close to the recited values or ranges such that the invention can perform as intended, such as having a desired degree of crosslinking and/or a desired lack of free radicals, as is apparent to the skilled person from the teachings contained herein. This is due, at least in part, to the  
20 varying properties of polymer compositions. Thus these terms encompass values beyond those resulting from systematic error.

Polymeric Material:

Ultra-high molecular weight polyethylene (UHMWPE) refers to linear non-branched chains of ethylene having molecular weights in excess of about 500,000,  
25 preferably above about 1,000,000, and more preferably above about 2,000,000. Often the molecular weights can reach about 8,000,000 or more. By initial average molecular weight is meant the average molecular weight of the UHMWPE starting material, prior to any irradiation. See US Patent 5,879,400, PCT/US99/16070, filed on July 16, 1999, and PCT/US97/02220, filed February 11, 1997, the entirety of  
30 which are hereby incorporated by reference.

The products and processes of this invention also apply to various types of polymeric materials, for example, a polyolefin, including high-density-polyethylene, low-density-polyethylene, linear-low-density-polyethylene, ultra-high molecular weight polyethylene (UHMWPE), or mixtures thereof. Polymeric materials, as used  
5 herein, also applies to polyethylene of various forms, for example, resin powder, flakes and particles.

Sterilization Steps:

The present invention relates to a method of sterilizing medical implants comprising a polymeric material, such as cross-linked UHMWPE, that is in contact  
10 with another piece, thereby forming an interface, comprising the steps of: a) sterilizing an interface by ionizing radiation; b) reducing free radicals in the UHMWPE under inert conditions; c) heating the medium to above the melting point of the irradiated UHMWPE (above about 137°C) to eliminate the crystalline matter and allow for the recombination/elimination of the residual free radicals and d) sterilizing the medical  
15 implant with a gas.

UHMWPE can be cross-linked by a variety of approaches, including those employing cross-linking chemicals (such as peroxides and/or silanes) and/or irradiation. Preferred approaches for cross-linking employ irradiation. Crossed linked UHMWPE can be obtained according to the teachings of US Patent 5,879,400 and  
20 PCT/US97/02220.

Interface:

The term interface in this invention is defined as the niche in medical devices formed when an implant is in a configuration where the UHMWPE is in contact with another piece (such as a metallic or a non-metallic component), which forms an  
25 interface between the polymer and the metal or another polymeric material. For example, interfaces of polymer-polymer or polymer-metal in medical prosthesis such as, orthopedic joints and bone replacement parts, e.g., hip, knee, elbow or ankle replacements.

Medical implants containing factory-assembled pieces that are in close contact with the UHMWPE form interfaces. In most cases, the interfaces are not readily accessible to EtO gas or the GP during a gas sterilization process.

Irradiation:

5        In one aspect of the invention, the type of radiation, preferably ionizing, is used. According to another aspect of the invention, a dose of ionizing radiation ranging from about 25 kGy to about 1000 kGy, preferably between about 50 kGy and about 100 kGy is used. The radiation dose can be about 50 kGy, about 100 kGy, about 200 kGy, about 300 kGy, about 400 kGy, about 500 kGy, about 600 kGy, about  
10   700 kGy, about 800 kGy, about 900 kGy, or about 1000 kGy, or any integer therebetween. These types of radiation, including gamma and/or electron beam, kills or inactivates bacteria, viruses, or other microbial agents potentially contaminating medical implants, including the interfaces, thereby achieving product sterility. The irradiation, which may be electron or gamma irradiation, in accordance with the  
15   present invention is carried out in air atmosphere containing oxygen, wherein the oxygen concentration in the atmosphere is at least 1%, 2%, 4%, or up to about 22%, or any integer thereabout or therebetween. In another aspect, the irradiation is carried out in an inert atmosphere, wherein the atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination  
20   thereof. The irradiation also can be carried out in a vacuum.

      In accordance with a preferred feature of this invention, the irradiation may be carried-out in a sensitizing atmosphere. This may comprise a gaseous substance which is of sufficiently small molecular size to diffuse into the polymer and which, on irradiation, acts as a polyfunctional grafting moiety. Examples include substituted or  
25   unsubstituted polyunsaturated hydrocarbons; for example, acetylenic hydrocarbons such as acetylene; conjugated or unconjugated olefinic hydrocarbons such as butadiene and (meth)acrylate monomers; sulphur monochloride, with chloro-trifluoroethylene (CTFE) or acetylene being particularly preferred. By "gaseous" is meant herein that the sensitizing atmosphere is in the gas phase, either above or below  
30   its critical temperature, at the irradiation temperature.

Metal Piece:

In accordance with the invention, the piece forming an interface with polymeric material is, for example, a metal. The metal piece in functional relation with polyethylene, according to the present invention, can be made of a cobalt chrome alloy, stainless steel, titanium, titanium alloy or nickel cobalt alloy, for example.

Non-metallic Piece:

In accordance with the invention, the piece forming an interface with polymeric material is, for example, a non-metal. The non-metal piece in functional relation with polyethylene, according to the present invention, can be made of ceramic material, for example.

Inert Atmosphere:

The term "inert atmosphere" refers to an environment having no more than 1% oxygen and more preferably, an oxidant-free condition that allows free radicals in polymeric materials to form cross links without oxidation during a process of sterilization. An inert atmosphere is used to avoid O<sub>2</sub>, which would otherwise oxidize the medical device comprising a polymeric material, such as UHMWPE. Inert atmospheric conditions such as nitrogen, argon, helium, neon, or vacuum are used for sterilizing polymeric medical implants by ionizing radiation.

Inert atmospheric conditions such as nitrogen, argon, helium, neon, or vacuum are also used for sterilizing interfaces of polymeric-metallic and/or polymeric-polymeric in medical implants by ionizing radiation.

Vacuum:

The term "vacuum" refers to an environment having no appreciable amount of gas that allows free radicals in polymeric materials to form cross links without oxidation during a process of sterilization. An vacuum is used to avoid O<sub>2</sub>, which would otherwise oxidize the medical device comprising a polymeric material, such as UHMWPE. A vacuum condition can be used for sterilizing polymeric medical implants by ionizing radiation.

A vacuum condition can be created using a commercially available vacuum pump. A vacuum condition also can be used when sterilizing interfaces of polymeric-metallic and/or polymeric-polymeric in medical implants by ionizing radiation.

Residual Free Radicals:

5 "Residual free radicals" refers to free radicals that are generated when a polymer is exposed to ionizing radiation such as gamma or e-beam irradiation. While some of the free radicals recombine with each other to form crosslinks, some become trapped in crystalline domains. The trapped free radicals are also known as residual free radicals.

10 According to one aspect of the invention, the levels of residual free radicals in the polymer generated during an ionizing radiation (such as gamma or electron beam) is preferably determined using electron spin resonance and treated appropriately to reduce free radicals.

Heating Process:

15 One aspect of the present invention discloses a process of reducing free radicals in polymeric component of a medical implant during the manufacturing process by heating for a time period depending on the melting temperature of the polymeric material. For example, the preferred temperature is about 137°C or more. Another aspect of the invention discloses a heating step that is carried in the air, in an atmosphere, containing oxygen, wherein the oxygen concentration is at least 1%, 2%,  
20 4%, or up to about 22%, or any integer thereabout or therebetween. In another aspect, the invention discloses a heating step that is carried while the implant is in contact with an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof. In another aspect, the invention discloses a heating step that is carried while  
25 the implant is in contact with a non-oxidizing medium, such as a fluid medium, wherein the medium contains no more than about 1% oxygen. In another aspect, the invention discloses a heating step that is carried while the implant is in a vacuum.

30 In another aspect of this invention, there is described the heating method of implants to reduce residual free radicals. The medical device comprising a polymeric

raw material, such as UHMWPE, is generally heated to a temperature of about 137°C or more. The medical device is kept heated in the inert medium until the concentration of the residual free radicals is reduced to acceptable levels as measured by electron spin resonance. It is preferred that the concentration of the residual free radicals is at or below the detection limit of electron spin resonance.

Soaking Process:

The present invention also provides conditions of treatment of reducing residual free radicals by soaking the implant in a sensitizing atmosphere such as immersing the implant into acetylene or another sensitizing gas which can be pressured into the implant. In this process, the sensitizing gas diffuses in and reacts with residual free radicals forming additional cross-links. The invention further relates to a process, if necessary, to accelerate the diffusion of the sensitizing gas by increasing temperature of the chamber that holds the implant and the gas.

The term "contacted" in this context includes close physical proximity with or touching such that the sensitizing agent can perform its intended function. Preferably, a polyethylene composition or pre-form is sufficiently contacted such that it is soaked in the sensitizing agent, which ensures that the contact is sufficient. Soaking is defined as placing the sample in a specific environment for a sufficient period of time at an appropriate temperature. The environment include a sensitizing gas, such as acetylene, ethylene, or a similar gas or mixture of gases, or a sensitizing liquid, for example, a diene. The environment is heated to a temperature ranging from room temperature to a temperature above the melting point of the polymeric material. The contact period ranges from at least about 1 minute to several weeks and the duration depending on the temperature of the environment. In one aspect, the contact time period at room temperature is about 24 hours to about 48 hours and preferably about 24 hours.

A "sensitizing environment" refers to a mixture of gases and/or liquids (at room temperature) that contain sensitizing gaseous and/or liquid component(s) that can react with residual free radicals to assist in the recombination and elimination of the residual free radicals. The gases may be acetylene, chloro-trifluoro ethylene

(CTFE), ethylene, or like. The gases or the mixtures of gases thereof may contain noble gases such as nitrogen, argon, neon and like. Other gases such as, carbon dioxide or carbon monoxide may also be present in the mixture. In applications where the surface of a treated material is machined away during the device manufacture, the gas blend could also contain oxidizing gases such as oxygen. The sensitizing environment can be dienes with different number of carbons, or mixtures of liquids and/or gases thereof. An example of a sensitizing liquid component is octadiene or other dienes, which can be mixed with other sensitizing liquids and/or non-sensitizing liquids such as a hexane or a heptane. A sensitizing environment can include a sensitizing gas, such as acetylene, ethylene, or a similar gas or mixture of gases, or a sensitizing liquid, for example, a diene. The environment is heated to a temperature ranging from room temperature to a temperature above the melting point of the polymeric material.

The invention is further described by the following examples, which do not limit the invention in any manner.

### Examples

#### **Example 1: Compression molding, mechanical interlocks in medical devices, and irradiation of hybrid components:**

Figure 1 diagrams sequential steps in compression molding of polyethylene powder to a metallic mesh. Figure 1A shows a mesh-like surface (20) on the other side facing the polyethylene powder (10) is compression molded. Figure 1B shows the consolidated polyethylene (15) taking a shape at the interface that penetrates into the mesh and Figure 1C depicting consolidated polyethylene partially penetrating the metallic mesh and forming a hybrid component (30) with an interlocking interface. The mesh surface on the other side is continuous through the interface or intermittent. Following compression molding, the hybrid component is irradiated, melted and then machined for final shape.

Polyethylene resin powder was placed on top of a metallic mesh as shown in 1A. These were then placed in a mold as shown in 1B, heated to above the melting



point and consolidated under pressure. Subsequent to pressing, the polyethylene was allowed to cool down to room temperature under pressure. The consolidated polyethylene was then removed from the mold to be irradiated to crosslink the polyethylene and melted to reduce the concentration of residual free radicals to an undetectable level. A final implant shape was then machined and the implant was  
5 sterilized with EtO, gas plasma or autoclaved. Extrusion of polyethylene on the other side of the mesh can be avoided by either having a solid layer of thin metal half-way through the mesh or by filling the empty pores on the backside with a space filling material that can be removed subsequent to the consolidation.

10 Referring to Figure 2, the diagram in Figure 2A shows an example of a compression molded polyethylene (60) to a metallic back (40) containing metallic mesh (20) and a metallic backed Patella (70). Figure 2B shows an example of a compression molded of polyethylene (120) to a metal shell (100) containing metallic mesh (20). Figures 2C and 2D show examples of a metal tray (40) containing  
15 metallic mesh (20) and undercuts or recess (80), respectively, to secure compression molded polyethylene.

A surface with geometries, for example, mesh, recess, undercuts, grooves (see Figures 2C and 2D), or the like that allowed the polyethylene resin powder to penetrate, consolidate and take the shape of the surface such that the mechanical  
20 interlocking is achieved and resulted into a hybrid component (30) having strong interlocking interface (see Figure 1C).

As shown in Figure 2A, polyethylene resin powder was consolidated to a mesh surface that has a solid metal backing for the manufacture of a patellar implant. The consolidated group was irradiated to crosslink the polyethylene and to sterilize the  
25 polyethylene/metallic mesh interface. Subsequently, the implant was melted to reduce the concentration of residual free radicals. The articulating surface of the implant was then machined to the desired geometry. Finally the implant was sterilized using a gas (ethylene oxide, gas plasma, or the other gas).

Figure 2B shows the same as in 2A, however, polyethylene resin powder was  
30 consolidated to a mesh surface in a different geometry.

Figures 2C and 2D depict two alternative counterface interlocking geometries. Figure 2C shows an intermittent metallic mesh on a solid metallic back, wherein the mesh acts as the interlocking counterface. The intermittent mesh on a solid metal backing can be used in a variety of geometries such as a tibial knee insert, bipolar acetabular component, acetabular component, patellar components, or shoulder glenoid. Figure 2D shows an undercut geometry into which polyethylene provides interfacial strength between the polyethylene and the metallic back. The shape and dimensions of the undercut can be varied to improve the interface strength. This type of interface geometry can be used in a variety of flat, concave, or convex interface geometries in a variety of implants.

As shown in Figures 2A, 2B, 2C and 2D, the consolidated polyethylene can penetrate the full thickness of the metallic mesh. However, sufficient interface strength can be achieved even with partial penetration.

Figure 2A depicts a combination of interface surfaces, for example, a mesh (20) and a macro-geometries is combined to tailor an interface of preferred strength.

A surface with geometries such as recess, undercuts (80), grooves (see Figures 2D) or like that allowed the polymeric material to penetrate and consolidate taking the shape of that surface such that the mechanical interlocking achieved allows for a strong interface.

Figure 2B shows a polyethylene (120), which is direct compression molded to a metallic mesh counterface (20) and/or a metal back metal shell (100) with a mechanical interlock, thereby forming a hybrid component. The hybrid component was irradiated using ionizing radiation to a desired dose level, for example, about 25 kGy to about 1000 kGy, preferably between about 50 kGy and about 100 kGy. Irradiation crosslinked the polymer, as well as sterilized the interface that is in close contact between the polyethylene and counterface. During the process of irradiation, residual free radicals were generated, which may compromise the long-term oxidative stability of the polymer and in vivo device performance. Therefore, a melting step at this point in the fabrication is used to quench the residual free radicals. Because the

resin powder was consolidated into the shape of the interface, which sets the shape memory of the polymer, the polyethylene did not separate from the counterface.

**Example 2: Melting of interlocked interface in a non-oxidizing medium:**

A medical device, for example, manufactured following a process as described in the examples 1 or 2, was immersed in a non-oxidizing medium such as inert gas or inert fluid. The medium was heated to above the melting point of the irradiated UHMWPE (about  $>137^{\circ}\text{C}$ ) to eliminate the crystalline matter and allowed for the recombination/elimination of the residual free radicals. Because the shape memory of the compression molded polymer is set at the mechanically interlocked interface and that memory is strengthened by the crosslinking step, there was no significant separation at the interface between the polyethylene and the counterface.

**Example 3: Post-melting machining and sterilization:**

The interface between the metal and the polymer becomes sterile during the high dose irradiation used to manufacture a hybrid component following a process as described above in examples 1 and 2. When there is a substantial oxidation of the outside surface of the polyethylene, one can further machine this surface to remove the oxidized surface layer. This requires to oversize the outside surfaces (near net-shape) or not even forming the outside surface geometry during the compression molding process. In the case a post-melting machining step, the melting step also can be carried out in an inert gas.

At this point in the fabrication of the device, because the interface is sterile but the rest of the component is not, the implant is sterilized with ethylene oxide, gas plasma, or the other gas.

**Example 4: Preparation of a polyethylene/mesh assembly by high temperature compression of a consolidated polyethylene cylinder to a metallic mesh:**

A custom-built, two-piece stainless steel die (Figure 3), with central cylindrical cavity (diam. = 11 mm) and accompanying stainless steel plunger (diam. = 10.5 mm) was used in the compression molding experiments.

A SS304 woven wire mesh (Southwestern Wire Cloth, Tulsa, OK) with 20 mesh per inch, 0.016" wire diameter, 0.034" opening width, 46.2% open area was used along with a machined cylindrical pin of GUR 1050 ultra-high molecular weight (Perplas Ltd., Bacup, UK) with a diameter of 9 mm and height of 13 mm were used in  
5 the compression experiments.

First, a section of mesh was cut to drop into the central cylindrical cavity of the die. Next, the UHWMPE pin was placed inside the cavity. The plunger was added atop of the pin/mesh tandem, and the entire die assembly was heated to 160 °C under vacuum (Lindberg/Blue Vacuum Oven, Asheville, NC), allowing the UHMWPE pin  
10 to fully melt before pressing. Following heating, approximately 3,500 lbs of load was applied to the plunger using a Carver Hydraulic Press (Unit #3912, Wabash, IN). Once this maximum load level was reached, the die assembly was held under load for approximately 20 minutes, allowing load to decay as consolidation and/or creep occurred.

15 Five pin/mesh assemblies were fabricated. A typical example showing the mesh incorporated into the UHMWPE pin is displayed in Figure 4.

**Example 5: Compression molding of polyethylene resin powder to a metallic mesh:**

A custom-built, two-piece stainless steel die (Figure 3), with central  
20 cylindrical cavity (diam. = 11 mm) and accompanying stainless steel plunger (diam. = 10.5 mm) was used in the compression molding experiments.

A SS304 woven wire mesh (Southwestern Wire Cloth, Tulsa, OK) with 60 mesh per inch, 0.0075" wire diameter, 0.0092" opening width, and 30.5% open area was used along with GUR 1050 ultra-high molecular weight virgin resin (Perplas  
25 Ltd., Bacup, UK) flakes were used in the consolidation experiments.

First, a section of mesh was cut to drop into the central cylindrical cavity of the die. Next, the cavity was densely packed with UHMWPE resin powder. The plunger was added atop of the resin/mesh tandem, and the entire die assembly was heated to 210°C under vacuum (Lindberg/Blue Vacuum Oven, Asheville, NC),  
30 allowing samples to fully melt before pressing. Following heating approximately

3,500 lbs of load was applied to the plunger using a Carver Hydraulic Press (Unit #3912, Wabash, IN). Once this maximum load level was reached, the die assembly was held under load for approximately 20 minutes, allowing load to decay as consolidation and/or creep occurred.

5        Five compression molded resin/mesh assemblies were fabricated. A typical example showing the mesh incorporated into polyethylene is displayed in Figure 5.

**Example 6: Fabrication of a crosslinked UHMWPE incorporated into a metal-mesh backing with a sterile interface:**

10        Five of the UHMWPE resin/mesh assemblies described in Example 5 were packaged in a metallized foil pouch in vacuum and subjected to 100 kGy gamma irradiation under vacuum (Steris-Isomedix, Northborough, MA). The faces of the UHMWPE resin/mesh assemblies that incorporated the mesh were photographed after irradiation. The UHMWPE resin/mesh assemblies were then heated to 160°C in a vacuum to eliminate the residual free radicals generated by the gamma irradiation.

15        The faces containing the mesh were photographed again following the melting. In all five samples the mesh was retained in the consolidated UHMWPE following the melting. In the present example, the shape memory of the UHMWPE was set to a geometry that included the mesh unlike what was observed in Example 4, where the shape memory recovery of the original dimensions of the pin led to the dissociation of the mesh. Figure 6 shows a typical example of the retention of the mesh following

20        post-irradiation melting.

         Therefore, the polyethylene resin needs to be consolidated to a original shape memory that also includes the metallic structure of interest to avoid dissociation following post-irradiation melting.

25        It is to be understood that the description, specific examples and data, while indicating exemplary embodiments, are given by way of illustration and are not intended to limit the present invention. Various changes and modifications within the present invention will become apparent to the skilled artisan from the discussion, disclosure and data contained herein, and thus are considered part of the invention.

**What is claimed is:**

1. A method of making a medical implant containing crosslinked polyethylene that is in contact with another piece, thereby forming an interface, wherein the method  
5 comprises:
  - a) compression molding of polyethylene to another piece, thereby forming an interlocked hybrid material;
  - b) irradiating the hybrid material by ionizing radiation; and
  - c) reducing free radicals in the crosslinked polyethylene by heating the  
10 hybrid material above the melting point of the crosslinked polyethylene.
2. The method according to claim 1, wherein the polyethylene comprises polyethylene resin powder, flakes, or particles, and wherein the polyethylene is compression molded to a metallic back.
- 15 3. The method according to claim 1, wherein the metallic back is shaped to serve as a fixation interface with the bone, through either bony growth or by bone cement.
4. The method according to claim 1, wherein the shapes are in the form of acetabular liner, tibial tray for total or unicompartmental knee implants, patella tray, glenoid component, ankle, elbow or finger component.
- 20 5. The method according to claim 1, wherein the irradiation is carried out in an atmosphere containing between about 1% and about 22% oxygen.
6. The method according to claim 1, wherein the irradiation is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.
- 25 7. The method according to claim 1, wherein the irradiation is carried out in a vacuum.

8. The method according to claim 1, wherein the heating temperature is above about 137°C.
9. The method according to claim 1, wherein the heating is carried out in an atmosphere containing between about 1% and about 22% oxygen.
- 5 10. The method according to claim 1, wherein the heating is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.
11. The method according to claim 1, wherein the heating is carried out in a vacuum.
12. The method according to claim 1, wherein the radiation dose is between about 25  
10 and about 1000 kGy.
13. The method according to claim 1, wherein the radiation dose is about 50 kGy, about 100 kGy, about 200 kGy, about 300 kGy, about 400 kGy, about 500 kGy, about 600 kGy, about 700 kGy, about 800 kGy, about 900 kGy, or about 1000 kGy.
14. The method according to claim 1, wherein the piece is metallic or non metallic.
- 15 15. The method according to claim 1, wherein the piece is a metallic or a non metallic back, a ceramic, a tibial tray, a patella tray, or an acetabular shell.
16. The method of claim 1, wherein the piece comprises a metallic or a non-metallic mesh, an undercut, a recess or a combination thereof.
17. The method according to claim 1, wherein the interface is a metal-polymer.
- 20 18. The polymer according to claim 17 is a polyolefin.
19. The polyolefin of claim 18 is selected from a group consisting of a low-density polyethylene, high-density polyethylene, linear low-density polyethylene, ultra-high molecular weight polyethylene (UHMWPE), or mixtures thereof.
20. The method according to claim 1, wherein the implant comprises medical devices  
25 selected from the group consisting of bipolar hip replacements, tibial knee inserts with reinforcing metallic and polyethylene posts, and an implant that contains an interface that cannot be sterilized by a gas sterilization method.

21. The method according to claim 1, wherein the ionizing radiation is a gamma irradiation in a nitrogen atmosphere.
22. The method according to claim 1, wherein the ionizing radiation is an electron beam irradiation in a nitrogen atmosphere.
- 5 23. The method according to claim 1, wherein the reduction of free radicals in the crosslinked polyethylene is achieved by heating the implant in contact with a non-oxidizing medium.
24. The method according to claim 1, wherein the reduction of free radicals in the crosslinked polyethylene is achieved by contacting with a non-oxidizing medium and  
10 heating the medium to above the melting temperature of the irradiated polyethylene.
25. The method according to claim 24, wherein the non-oxidizing medium is an inert gas.
26. The method according to claim 24, wherein the non-oxidizing medium is an inert fluid.
- 15 27. The method according to claim 24, wherein the medium is a polyunsaturated hydrocarbon selected from the group consisting of: acetylenic hydrocarbons such as acetylene; conjugated or unconjugated olefinic hydrocarbons such as butadiene and (meth)acrylate monomers; and sulphur monochloride with chloro-tri-fluoroethylene (CTFE) or acetylene.
- 20 28. The method according to claim 1, wherein the reduction of free radicals in the crosslinked polyethylene is achieved by heating the implant to above the melting point of the polyethylene.
29. The method according to claim 1, wherein the reduction of free radicals in crosslinked polyethylene is achieved under an inert condition having no more than  
25 about 1% oxygen.
30. The method according to claim 29, wherein the condition is an inert atmosphere or a vacuum.



31. The method according to claim 30, wherein the inert atmosphere contains a gas selected from the group consisting of: nitrogen; argon; helium; and neon.
32. The method according to claim 1, wherein the implant is further sterilized by a gas.
- 5 33. The method according to claim 32, wherein the gas is ethylene oxide, gas plasma, or other gas.
34. The method according to claim 33, wherein ethylene oxide is used for sterilization.
35. The method according to claim 33, wherein gas plasma is used for sterilization.
- 10 36. A method of forming and sterilizing a medical implant containing crosslinked polyethylene that is in contact with another piece, thereby forming an interface, wherein the method comprises the steps of:
  - a) compression molding of polyethylene resin powder to another piece, thereby forming an interlocked hybrid material;
  - 15 b) irradiating the hybrid material by ionizing radiation;
  - c) reducing free radicals in the crosslinked polyethylene by heating the hybrid material above the melting point of the crosslinked polyethylene; and
  - d) sterilizing the medical implant with a gas.
- 20 37. The method according to claim 36, wherein the irradiation is carried out in an atmosphere containing between about 1% and about 22% oxygen.
38. The method according to claim 36, wherein the irradiation is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.
- 25 39. The method according to claim 36, wherein the irradiation is carried out in a vacuum.

40. The method according to claim 36, wherein the heating is carried out in an atmosphere containing between about 1% and about 22% oxygen.
41. The method according to claim 36, wherein the heating is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group  
5 consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.
42. The method according to claim 36, wherein the heating is carried out in a vacuum.
43. A method of forming and sterilizing a medical implant containing crosslinked polyethylene that is in contact with another piece, thereby forming an interface,  
10 wherein the method comprises the steps of:
- a) compression molding of polyethylene to another piece, thereby forming an interlocked hybrid material;
  - b) irradiating the hybrid material by ionizing radiation;
  - c) reducing free radicals in the crosslinked polyethylene by heating the  
15 hybrid material above the melting point of the crosslinked polyethylene; and
  - d) sterilizing the medical implant with a gas.
44. The method according to claim 43, wherein the irradiation is carried out in an atmosphere containing between about 1% and about 22% oxygen.
- 20 45. The method according to claim 43, wherein the irradiation is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.
46. The method according to claim 43, wherein the irradiation is carried out in a vacuum.
- 25 47. The method according to claim 43, wherein the heating is carried out in an atmosphere containing between about 1% and about 22% oxygen.

48. The method according to claim 43, wherein the heating is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

49. The method according to claim 43, wherein the heating is carried out in a vacuum.

50. A medical implant containing crosslinked polyethylene that is in contact with another piece, thereby forming an interface, obtainable by:

- a) compression molding of polyethylene resin powder to another piece, thereby forming an interlocked hybrid material;
- b) irradiating the hybrid material by ionizing radiation; and
- c) reducing free radicals in the crosslinked polyethylene by heating the hybrid material above the melting point of the crosslinked polyethylene.

51. The medical implant of claim 50, wherein the polyethylene is in contact with another piece, thereby forming an interlocking interface.

52. The medical implant of claim 50, wherein the interface is rendered substantially sterile.

53. The method according to claim 50, wherein the irradiation is carried out in an atmosphere containing between about 1% and about 22% oxygen.

54. The method according to claim 50, wherein the irradiation is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

55. The method according to claim 50, wherein the irradiation is carried out in a vacuum.

56. The method according to claim 50, wherein the heating is carried out in an atmosphere containing between about 1% and about 22% oxygen.

57. The method according to claim 50, wherein the heating is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

58. The method according to claim 50, wherein the heating is carried out in a vacuum.

59. A medical implant containing crosslinked polyethylene that is in contact with another piece, thereby forming an interface, obtainable by:

- a) compression molding of polyethylene to another piece, thereby forming an interlocked hybrid material;
- b) irradiating the hybrid material by ionizing radiation; and
- c) reducing free radicals in the crosslinked polyethylene by heating the hybrid material above the melting point of the crosslinked polyethylene.

60. The medical implant of claim 59, wherein the polyethylene is in contact with another piece, thereby forming an interlocking interface.

61. The medical implant of claim 59, wherein the interface is substantially sterile.

62. The method according to claim 59, wherein the irradiation is carried out in an atmosphere containing between about 1% and about 22% oxygen.

63. The method according to claim 59, wherein the irradiation is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

64. The method according to claim 59, wherein the irradiation is carried out in a vacuum.

65. The method according to claim 59, wherein the heating is carried out in an atmosphere containing between about 1% and about 22% oxygen.

66. The method according to claim 59, wherein the heating is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

67. The method according to claim 59, wherein the heating is carried out in a vacuum.

68. An interface obtainable by:

- a) compression molding of polyethylene resin powder to another piece, thereby forming an interlocked hybrid material;
- b) irradiating the hybrid material by ionizing radiation; and
- c) reducing free radicals in the polyethylene by heating the hybrid material above the melting point of the polyethylene.

69. The interface according to claim 68, wherein the piece is a metallic or a non-metallic component.

70. The interface according to claim 68, wherein the piece is a metallic back, a non-metallic back, a tibial tray, a patella tray, or an acetabular shell.

71. The interface of claim 68, wherein the piece comprises a metallic mesh, a non-metallic mesh, an undercut, a recess or a combination thereof.

72. The interface according to claim 68, wherein the interface is a metal-polymer.

73. The polymer according to claim 72 is a polyolefin.

74. The polyolefin of claim 73 is selected from a group consisting of a low-density polyethylene, high-density polyethylene, linear low-density polyethylene, ultra-high molecular weight polyethylene (UHMWPE), or mixtures thereof.

75. The method according to claim 68, wherein the irradiation is carried out in an atmosphere containing between about 1% and about 22% oxygen.

76. The method according to claim 68, wherein the irradiation is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

77. The method according to claim 68, wherein the irradiation is carried out in a vacuum.
78. The method according to claim 68, wherein the heating is carried out in an atmosphere containing between about 1% and about 22% oxygen.
- 5 79. The method according to claim 68, wherein the heating is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.
80. The method according to claim 68, wherein the heating is carried out in a vacuum.
- 10 81. An interface obtainable by:
- a) compression molding of polyethylene to another piece, thereby forming an interlocked hybrid material;
  - b) irradiating the hybrid material by ionizing radiation; and
  - c) reducing free radicals in the polyethylene by heating the hybrid
- 15 material above the melting point of the polyethylene.
82. The method according to claim 81, wherein the irradiation is carried out in an atmosphere containing between about 1% and about 22% oxygen.
83. The method according to claim 81, wherein the irradiation is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group
- 20 consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.
84. The method according to claim 81, wherein the irradiation is carried out in a vacuum.
85. The method according to claim 81, wherein the heating is carried out in an atmosphere containing between about 1% and about 22% oxygen.
- 25 86. The method according to claim 81, wherein the heating is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

87. The method according to claim 81, wherein the heating is carried out in a vacuum.
88. The interface according to claim 81, wherein the piece is a metallic or a non-metallic component.
- 5 89. The interface according to claim 81, wherein the piece is a metallic back, a non-metallic back, a tibial tray, a patella tray, or an acetabular shell.
90. The interface of claim 81, wherein the piece comprises a metallic mesh, a non-metallic mesh, an undercut, a recess or a combination thereof.
91. The interface according to claim 81, wherein the interface is a metal-polymer.
- 10 92. The polymer according to claim 91 is a polyolefin.
93. The polyolefin of claim 91 is selected from a group consisting of a low-density polyethylene, high-density polyethylene, linear low-density polyethylene, ultra-high molecular weight polyethylene (UHMWPE), or mixtures thereof.
94. An interface obtainable by:
  - 15 a) compression molding of resin powder to another piece, thereby forming an interlocked hybrid material; and
  - b) irradiating the hybrid material by ionizing radiation, wherein the interface is substantially sterile.
95. The method according to claim 94, wherein the irradiation is carried out in an atmosphere containing between about 1% and about 22% oxygen.
- 20 96. The method according to claim 94, wherein the irradiation is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.
97. The method according to claim 94, wherein the irradiation is carried out in a vacuum.
- 25 98. The interface according to claim 94, wherein the piece is a metallic or a non-metallic component.

99. The interface according to claim 94, wherein the piece is a metallic back, a non-metallic back, a tibial tray, a patella tray, or an acetabular shell.
100. The interface of claim 94, wherein the piece comprises a metallic mesh, a non-metallic mesh, an undercut, a recess or a combination thereof.
- 5 101. The interface according to claim 94, wherein the interface is a metal-polymer.
102. The polymer according to claim 101 is a polyolefin.
103. The polyolefin of claim 102 is selected from a group consisting of a low-density polyethylene, high-density polyethylene, linear low-density polyethylene, ultra-high molecular weight polyethylene (UHMWPE), or mixtures thereof.
- 10 104. An interface obtainable by:
- a) compression molding of polyethylene to another piece, thereby forming an interlocked hybrid material; and
  - b) irradiating the hybrid material by ionizing radiation, wherein the interface is substantially sterile.
- 15 105. The method according to claim 104, wherein the irradiation is carried out in an atmosphere containing between about 1% and about 22% oxygen.
106. The method according to claim 104, wherein the irradiation is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.
- 20 107. The method according to claim 104, wherein the irradiation is carried out in a vacuum.
108. The interface according to claim 104, wherein the piece is a metallic or a non-metallic component.
109. The interface according to claim 104, wherein the piece is a metallic back, a non-metallic back, a tibial tray, a patella tray, or an acetabular shell.
- 25 110. The interface of claim 104, wherein the piece comprises a metallic mesh, a non-metallic mesh, an undercut, a recess or a combination thereof.



111. The interface according to claim 104, wherein the interface is a metal-polymer.

112. The polymer according to claim 111 is a polyolefin.

113. The polyolefin of claim 112 is selected from a group consisting of a low-density polyethylene, high-density polyethylene, linear low-density polyethylene, ultra-high  
5 molecular weight polyethylene (UHMWPE), or mixtures thereof.

114. An interface obtainable by:

- a) compression molding of polyethylene resin powder to another piece, thereby forming an interlocked hybrid material;
- b) irradiating the hybrid material by ionizing radiation; and
- 10 c) reducing free radicals in the polyethylene by heating the hybrid material above the melting point of the polyethylene, wherein the interface is substantially sterile.

115. The method according to claim 114, wherein the irradiation is carried out in an atmosphere containing between about 1% and about 22% oxygen.

15 116. The method according to claim 114, wherein the irradiation is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

117. The method according to claim 114, wherein the irradiation is carried out in a vacuum.

20 118. The method according to claim 114, wherein the heating is carried out in an atmosphere containing between about 1% and about 22% oxygen.

119. The method according to claim 114, wherein the heating is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

25 120. The method according to claim 114, wherein the heating is carried out in a vacuum.

121. The interface according to claim 114, wherein the piece is a metallic or a non-metallic component.

122. The interface according to claim 114, wherein the piece is a metallic back, a non-metallic back, a tibial tray, a patella tray, or an acetabular shell.

5 123. The interface of claim 114, wherein the piece comprises a metallic mesh, a non-metallic mesh, an undercut, a recess or a combination thereof.

124. The interface according to claim 114, wherein the interface is a metal-polymer.

125. The polymer according to claim 124 is a polyolefin.

10 126. The polyolefin of claim 125 is selected from a group consisting of a low-density polyethylene, high-density polyethylene, linear low-density polyethylene, ultra-high molecular weight polyethylene (UHMWPE), or mixtures thereof.

127. An interface obtainable by:

- a) compression molding of polyethylene to another piece, thereby forming an interlocked hybrid material;
- 15 b) irradiating the hybrid material by ionizing radiation; and
- c) reducing free radicals in the polyethylene by heating the hybrid material above the melting point of the polyethylene, wherein the interface is substantially sterile.

128. The method according to claim 127, wherein the irradiation is carried out in an atmosphere containing between about 1% and about 22% oxygen.

129. The method according to claim 127, wherein the irradiation is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

130. The method according to claim 127, wherein the irradiation is carried out in a vacuum.

131. The method according to claim 127, wherein the heating is carried out in an atmosphere containing between about 1% and about 22% oxygen.

132. The method according to claim 127, wherein the heating is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

133. The method according to claim 127, wherein the heating is carried out in a vacuum.

134. The interface according to claim 127, wherein the piece is a metallic or a non-metallic component.

135. The interface according to claim 127, wherein the piece is a metallic back, a non-metallic back, a tibial tray, a patella tray, or an acetabular shell.

136. The interface of claim 127, wherein the piece comprises a metallic mesh, a non-metallic mesh, an undercut, a recess or a combination thereof.

137. The interface according to claim 127, wherein the interface is a metal-polymer.

138. The polymer according to claim 137 is a polyolefin.

139. The polyolefin of claim 138 is selected from a group consisting of a low-density polyethylene, high-density polyethylene, linear low-density polyethylene, ultra-high molecular weight polyethylene (UHMWPE), or mixtures thereof.

140. An acetabular assembly comprising:

a) polyethylene compression molded to another piece, thereby forming an interlocked hybrid component;

b) a substantially sterile interface; and

c) a metallic back.

141. The assembly of claim 140, wherein the piece comprising a metallic mesh, a non-metallic mesh, an undercut, a recess, or a combination thereof.

142. The assembly of claim 140, wherein the polyethylene comprises powder, flakes, or particles, and wherein the polyethylene is compression molded to a counterface.

143. The assembly of claim 142, wherein the counterface is metallic back, a metallic mesh, a tibial tray, a patella tray, or an acetabular shell.

144. The assembly of claim 142, wherein the counterface is shaped to serve as a fixation interface with the bone, through either bony growth or by bone cement.

145. The assembly of claim 144, wherein the shapes are in the form of acetabular liner, tibial tray for total or unicompartmental knee implants, patella tray, glenoid  
5 component, ankle, elbow or finger component.

146. The assembly of claim 140, wherein the polyethylene is crosslinked by ionizing radiation.

147. The method according to claim 146, wherein the irradiation is carried out in an atmosphere containing between about 1% and about 22% oxygen.

10 148. The method according to claim 146, wherein the irradiation is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

149. The method according to claim 146, wherein the irradiation is carried out in a vacuum.

15 150. The assembly of claim 146, wherein the radiation dose is between about 25 and about 1000 kGy.

151. The assembly of claim 146, wherein the radiation dose is about 50 kGy, about 100 kGy, about 200 kGy, about 300 kGy, about 400 kGy, about 500 kGy, about 600 kGy, about 700 kGy, about 800 kGy, about 900 kGy, or about 1000 kGy.

20 152. The assembly of claim 140, wherein the hybrid component is heated to a temperature above the melting point of the polyethylene.

153. The method according to claim 152, wherein the heating is carried out in an atmosphere containing between about 1% and about 22% oxygen.

154. The method according to claim 152, wherein the heating is carried out in an inert  
25 atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

155. The method according to claim 152, wherein the heating is carried out in a vacuum.
156. The assembly of claim 152, wherein the heating temperature is above about 137°C.
- 5 157. An acetabular assembly comprising:
- a) a polyethylene acetabular liner compression molded to another piece, thereby forming an interlocked hybrid material;
  - b) a substantially sterile interface; and
  - c) a metallic back.
- 10 158. The assembly of claim 157, wherein the comprising a metallic mesh, a non-metallic mesh, an undercut, a recess, or a combination thereof.
159. The assembly of claim 157, wherein the polyethylene comprises powder, flakes, or particles, and wherein the polyethylene is compression molded to a counterface.
160. The assembly of claim 159, wherein the counterface is metallic back, a metallic mesh, a tibial tray, a patella tray, or an acetabular shell.
- 15 161. The assembly of claim 159, wherein the counterface is shaped to serve as a fixation interface with the bone, through either bony growth or by bone cement.
162. The assembly of claim 161, wherein the shapes are in the form of acetabular liner, tibial tray for total or unicompartmental knee implants, patella tray, glenoid component, ankle, elbow or finger component.
- 20 163. The assembly of claim 157, wherein the polyethylene is crosslinked by ionizing radiation.
164. The method according to claim 163, wherein the irradiation is carried out in an atmosphere containing between about 1% and about 22% oxygen.
- 25 165. The method according to claim 163, wherein the irradiation is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.

166. The method according to claim 163, wherein the irradiation is carried out in a vacuum.
167. The assembly of claim 163, wherein the radiation dose is between about 25 and about 1000 kGy.
- 5 168. The assembly of claim 163, wherein the radiation dose is about 50 kGy, about 100 kGy, about 200 kGy, about 300 kGy, about 400 kGy, about 500 kGy, about 600 kGy, about 700 kGy, about 800 kGy, about 900 kGy, or about 1000 kGy.
169. The assembly of claim 157, wherein the hybrid component is heated to a temperature above the melting point of the polyethylene.
- 10 170. The method according to claim 169, wherein the heating is carried out in an atmosphere containing between about 1% and about 22% oxygen.
171. The method according to claim 169, wherein the heating is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or the like, or a combination thereof.
- 15 172. The method according to claim 169, wherein the heating is carried out in a vacuum.
173. The assembly of claim 169, wherein the heating temperature is above about 137°C.
174. A medical implant comprising crosslinked polyethylene having substantially no  
20 detectable free radicals; and a sterile interlocking interface.
175. The implant of claim 174, wherein the polyethylene is in contact with another piece, thereby forming an interface.
176. The implant of claim 174, wherein the polyethylene is compression molded to another piece, thereby forming a mechanically interlocked hybrid material.
- 25 177. The implant of claim 174, wherein the polyethylene resin powder is compression molded to another piece, thereby forming a mechanically interlocked hybrid material.

178. The implant of claim 174, wherein the polyethylene is in contact with another piece, thereby forming an interlocking interface.

179. The implant of claim 178, wherein the piece is a metallic or a non-metallic component.

5 180. The implant of claim 178, wherein the piece is a metallic back, a non-metallic back, a tibial tray, a patella tray, or an acetabular shell.

181. The implant of claim 178, wherein the piece comprises a metallic mesh, a non-metallic mesh, an undercut, a recess or a combination thereof.

182. The implant of claim 174, wherein the interface is a metal-polymer.

10 183. The polyethylene according to claim 174 is a polyolefin.

184. The polyolefin of claim 183 is selected from a group consisting of a low-density polyethylene, high-density polyethylene, linear low-density polyethylene, ultra-high molecular weight polyethylene (UHMWPE), or mixtures thereof.

185. The implant of claim 174, wherein the polyethylene comprises powder, flakes,  
15 or particles, and wherein the polyethylene is compression molded to a counterface.

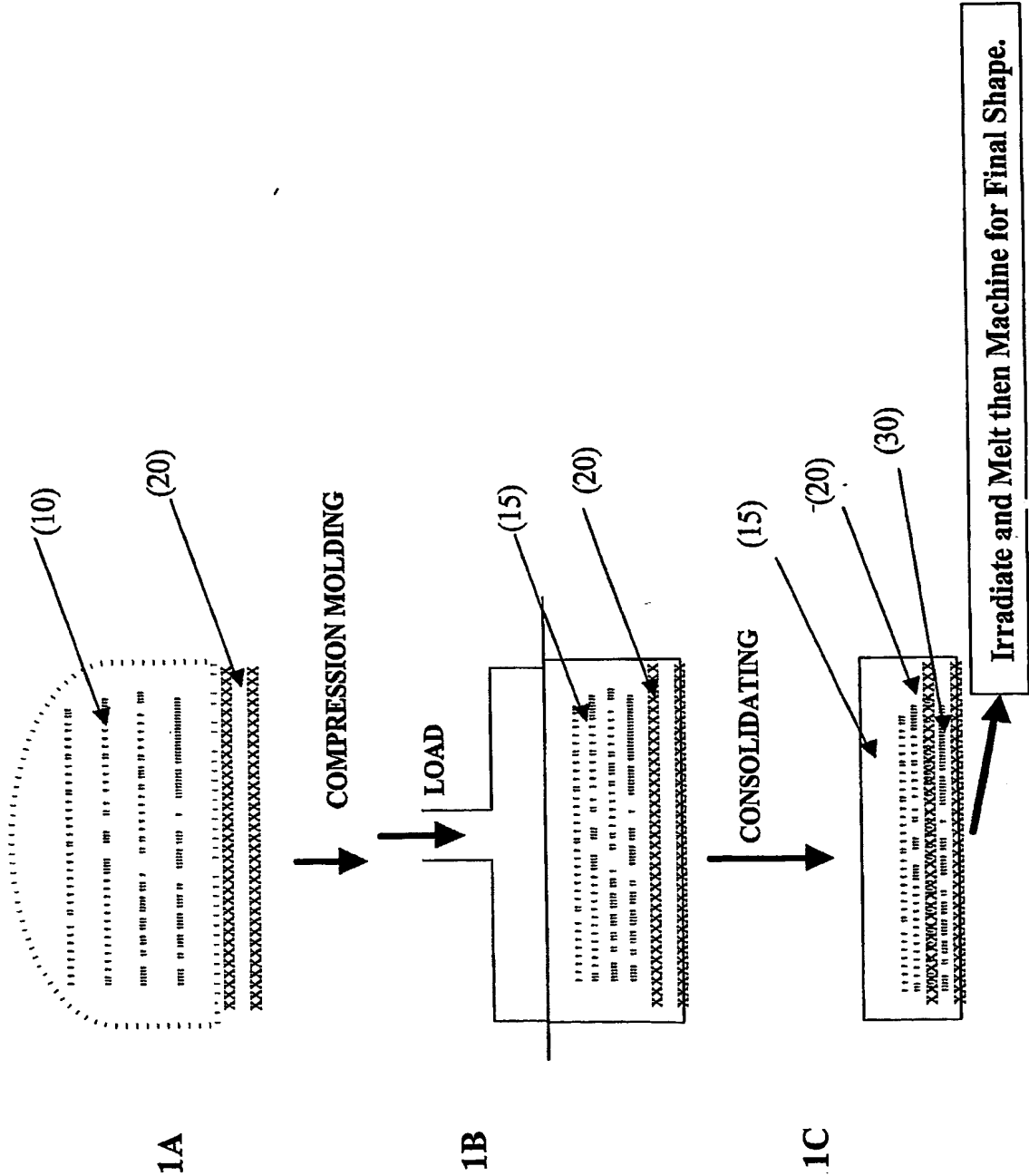
**Abstract**

The present invention relates to medical implants that comprise crosslinked polyethylene (such as UHMWPE) that is in contact with another piece (such as a metallic mesh or back, a non-metallic mesh or back, a tibial tray, a patella tray, or an acetabular shell), thereby forming an interface. Also disclosed herein are the methods  
5 of manufacturing and sterilizing such medical devices and materials used therein.



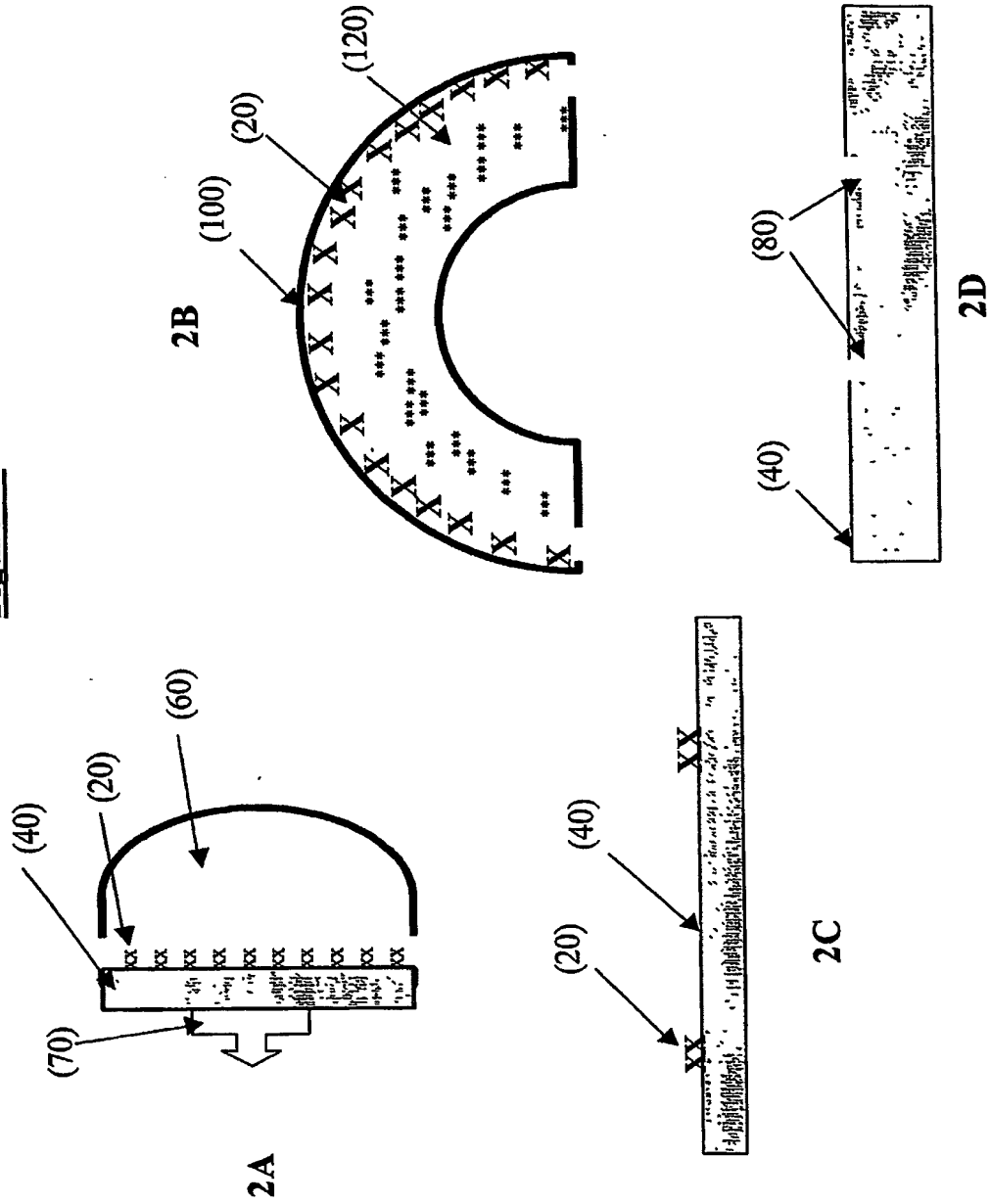
Title: Metal Back or Mesh Crosslinking  
 Inventor: Orhun K. Muratoglu and  
 William H. Harris  
 Docket No. 37697-0068

**Figure - 1**



Title: Metal Back or Mesh Crosslinking  
Inventor: Orhun K. Muratoglu and  
William H. Harris  
Docket No. 37697-0068

**Figure - 2**

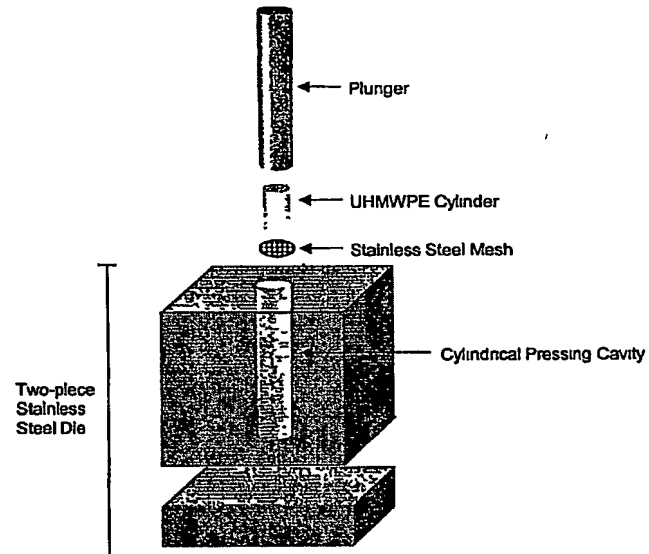


60424709-110802

Title: Metal Back or Mesh Crosslinking  
Inventor: Orhun K. Muratoglu and  
William H. Harris  
Docket No. 37697-0068

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Figure 3 :



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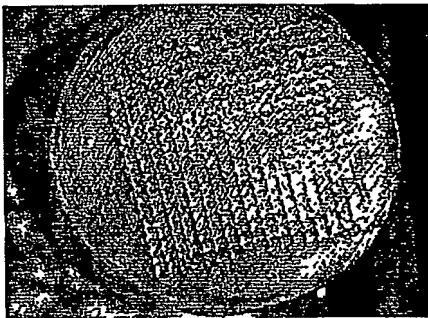
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**Figure 4:**

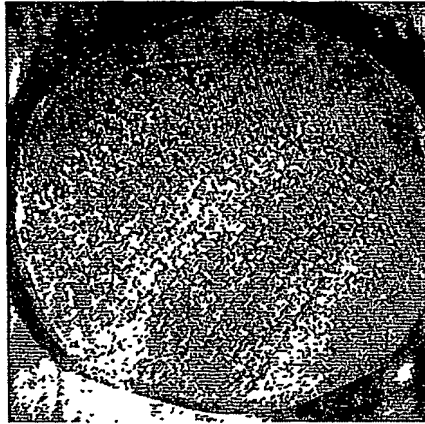


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William H. Harris  
Docket No. 37697-0068

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**Figure 5:**

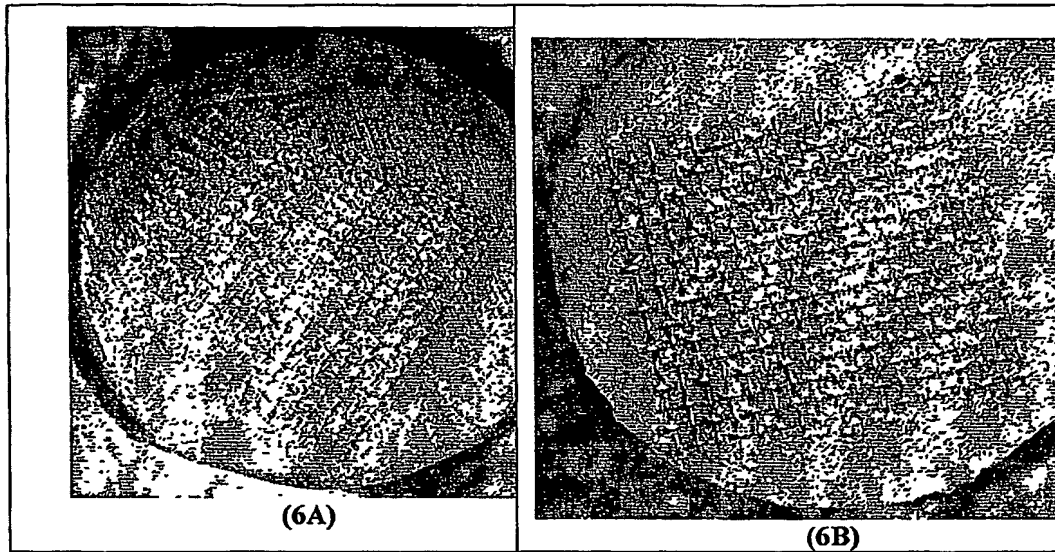


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William H. Harris  
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Figure 6:



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